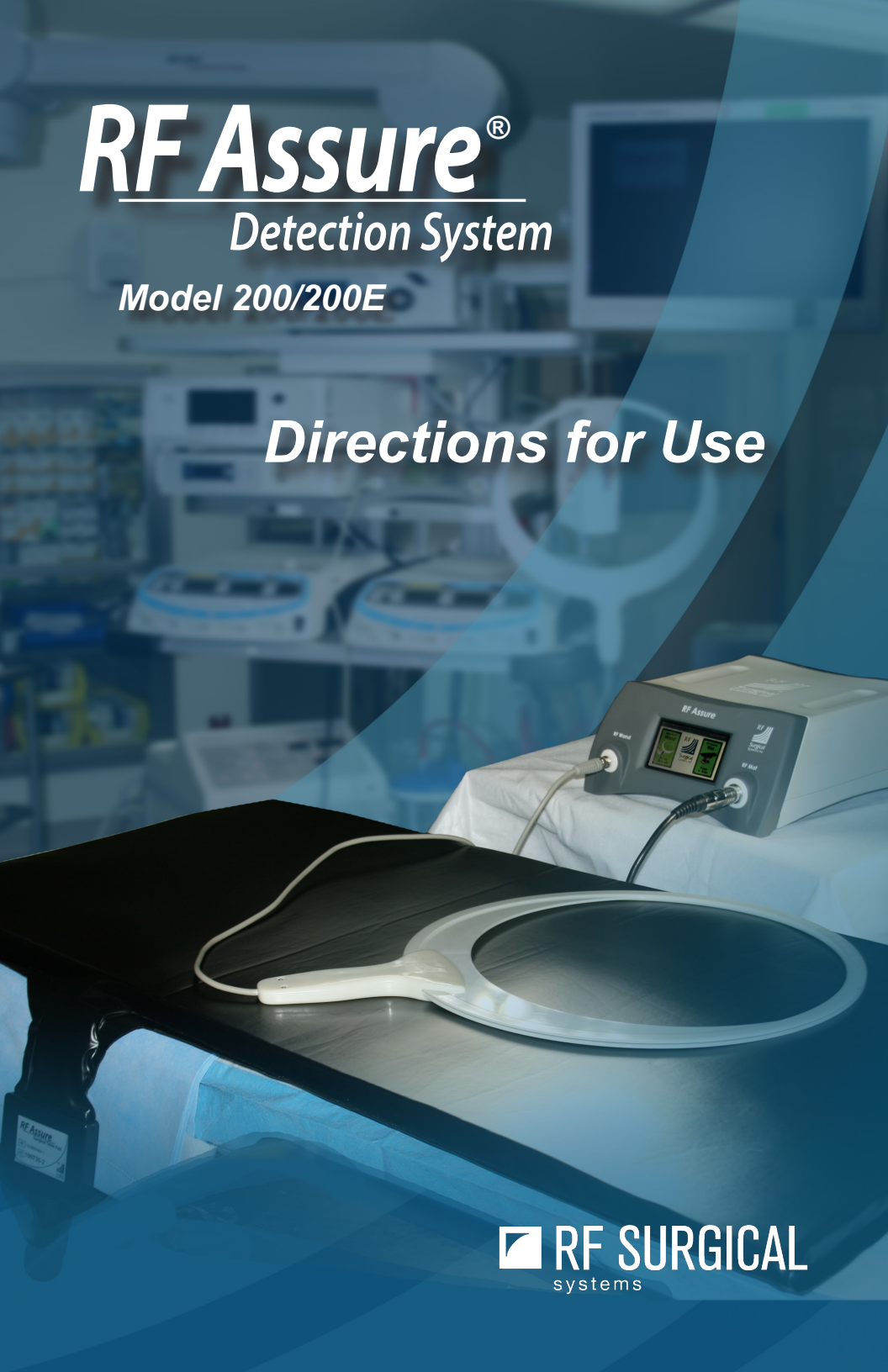
RF Assure®

Detection System

Model 200/200E

Directions for Use



RF SURGICAL
systems

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System Overview

The RF Assure™ Detection System is designed to provide a means for surgical staff to identify and recover retained tagged objects in a patient or in other areas of the operating room. The System is intended to be used in addition to established hospital safety procedures to prevent retained objects.

After a surgical procedure and before closing, the RF Assure Detection System provides an additional safety measure to check for retained gauze, towels and sponges in a patient.

The RF Assure Detection System consists of 4 (four) components:
1. Console
2. RF Tag and RF Tagged Gauze, Sponge & OR Towels
3. Blair-Port Wand®
4. RF Assure Antenna Array Body Scanner

Console

The console contains (1) the electronics that power and regulate the wand and Body Scanner, and (2) the control panel for user operation and for communication of system reports, status and alarms. The console is shipped with a medical grade power cord and a retaining strap. The RF Assure console Model 200/200E is designed to be used with the RF Assure Detection Antenna Array Body Scanner and Blair-Port Wand.

RF Tag and RF Tagged Gauze, Sponge & OR Towels

The tag is an electrically passive pellet-like device that is designed to resonate a magnetic signal when stimulated by magnetic impulses from the wand. The RF Tag is attached to surgical disposables (single use gauze, sponge, OR towels etc.) for detection of these items.

⚠ **Caution: Do not reuse single use disposables to avoid risk of cross contamination.**

Blair-Port Wand®

The wand is supplied sterile for single use or when covered can be reused. Wands intended for reuse must be covered with a sterile drape after removal from the sterile pack. The wand functions both as an antenna to transmit magnetic impulses that stimulate the RF tag, and as a receiver to detect the resonant signal returning from the tag.

RF Assure Antenna Array Body Scanner

The RF Assure Body Scanner contains a radiolucent (x-ray compatible) antenna in a gel pad. The reusable Body Scanner is placed on the OR table on top of the table pad and under the sterile drapes. When activated, the Body Scanner transmits magnetic impulses that stimulate the RF tag, and receives a resonant signal from the tag when detected. The RF Assure Body Scanner is designed to be used with the RF Assure Detection console Model 200/200E.

Patient Records

The RF Assure Detection System allows scan records to be kept and accessed through the Patient Records icon on the main display (see Console Settings and Reports section).

Patient Records can also be accessed from a remote computer when properly configured using an internet web address (see Patient Records - Remote Access section).

⚠ Warning

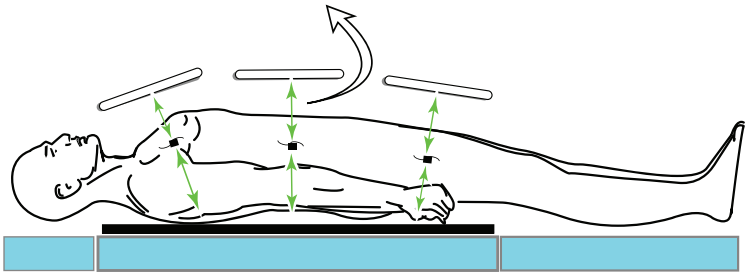
Observe all applicable hospital policy and HIPAA regulations in dealing with patient records.

Indications

The RF Assure Detection System is indicated to detect tagged objects, such as surgical gauze, towels and sponges, that are inside a patient during a surgical procedure in order to aid surgical staff in the recovery of those objects before closing. The System is intended for use by trained surgical staff in a surgical (operating room) setting.

The System is indicated for use as an adjunctive device to complement, not replace, established safety procedures prescribed to prevent retained objects.

Effective range up to 16" (40.64cm) from tag to wand or mat



The RF Assure Detection System has an effective range of up to 16" (40.64cm) depending on tag orientation.

Contraindications

The RF Assure Detection System is not recommended for use in situations and/or patients where the wand or Body Scanner cannot be located within the effective operating range from the farthest possible location of a tagged object.

The RF Assure Body Scanner is not recommended for patients with a body mass index (BMI) that exceeds the effective range. The Blair-Port Wand can be used with the Body Scanner to expand the detection coverage for high BMI patients.

The RF Assure Body Scanner is not intended to replace patient positioning devices or gel pads.

The System will only work with gauze, sponges and towels fitted with an RF Detect tag.

⚠ Warning

Do not use the System as a substitute for recommended practices for sponge, sharps, and instrument counts prescribed to prevent retained objects. The System is intended as a supplement to standard counting practices.

⚠ Caution

The RF tag is contained in a pouch attached to the gauze, towel or sponge. Damage to the tag or pouch may affect the system's ability to detect the tag.

The Body Scanner can be punctured by sharp objects. Replace the Body Scanner if it is damaged.

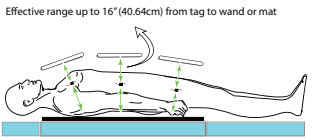
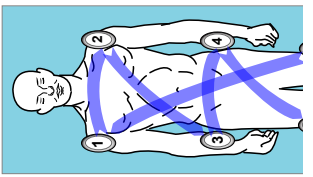
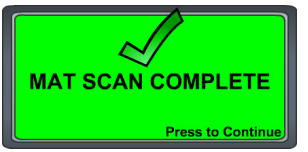
Unfolding gauze sponges can expose woven edges and X-ray member to damage.

System Operation

The RF Assure Detection System offers two modes of scanning for RF tagged gauze, sponges and OR towels. The Body Scanner is the primary detection method and scans the surgical site with one touch of the console display. The Blair-Port® Wand adds an extra measure of assurance by scanning the patient and areas outside of the surgical site to locate tagged objects. The Wand may require two people when presented into the sterile field and during scanning: one person for console observation and control, and one to scan (e.g., a circulating nurse and a sterile nurse or doctor).

Quick Start

Step	Process	System Feedback & Guidelines	
1	Plug in the Console power cord and turn the back panel switch to ON	After self-check, display screen shows main menu for system operation.	
2	Place the Body Scanner on top of table pad under drapes and connect Body Scanner cable to console	Display shows RF Assure Mat icon green if ready to scan	
3	Remove wand from package. If wand will be reused, cover with a sterile drape. Connect wand cable to console.	Circulating nurse can assist in connecting wand cable to console. Connect while holding wand in air away from metal for calibration. Wand icon shows green if ready to scan.	 **Main Menu**

4	Clear scan area	Remove all RF tagged items (used and unused gauze or sponges) from patient area by 36”.	
5	From main menu, select Setup & Reports to enter data, or touch a device icon to begin scanning.	Listen for the 3 fast beeps that indicate a scan start (or stop) and an audible “tic” sound when scanning. Scanning progress is displayed.	
6	With wand, scan as needed moving low and slow, close to patient’s body	Refer to scanning pattern. Observe console to verify scanning progress is displayed.	
7	Tag detected	Display shows “DETECTION” and a solid tone is audible. Refer to Scanning Situations and Suggested Responses	
8	No tag detected	The display shows “MAT SCAN COMPLETE”. Follow hospital protocol.	

1) Power Up the Console

Thread the retaining strap through the slots in the bottom of the console and secure the console to the equipment stand if desired. Plug the medical grade power cord provided with the console into the power input module, then insert cord into the snap clip on the back of the console. Then plug the power cord into a mains voltage source (wall outlet).

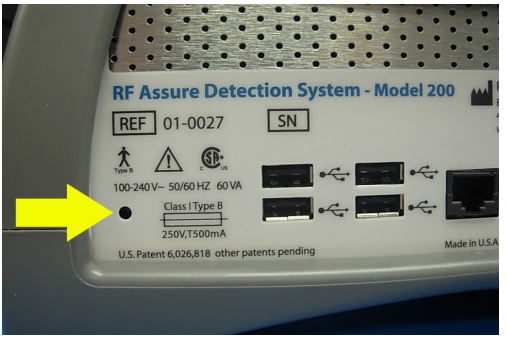
Set power switch to ON position. The display will illuminate for a period of time then display the Main Menu. If not, check power connections, power down system and try powering on again. If there is no display, contact your RF Surgical representative.

⚠ Caution

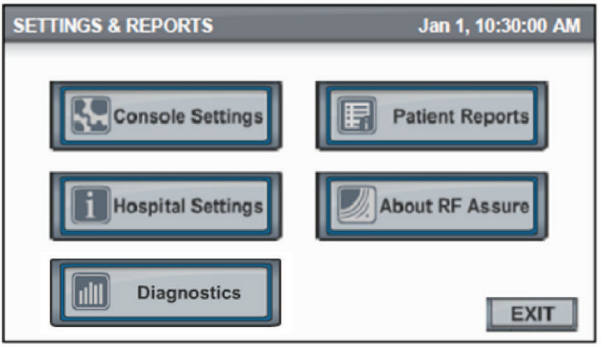
Do not plug any unapproved devices into the console.

2) Console Settings and Reports

To access the Console Settings and Reports menu, press the recessed button on the back panel.



Use a sharp object (paper clip or pen) to depress the button. The Settings and Reports menu will appear.



a) Console Settings – allows date and time, Ethernet configuration and audio levels to be set.

- Date & Time
  Select the time zone for your geographical area. Select the month, day, year and time using the touch screen drop down menus and keypad. Touch RETURN for Console Settings menu.

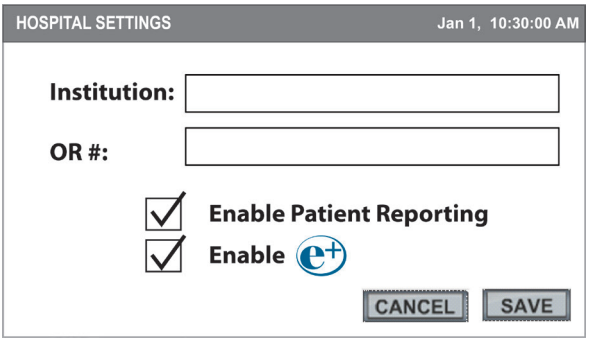
- Ethernet Configuration
  Allows an IP address to be accessed for remote web access of patient records. A static IP address is recommended for each console. Check with hospital IT department for appropriate settings.

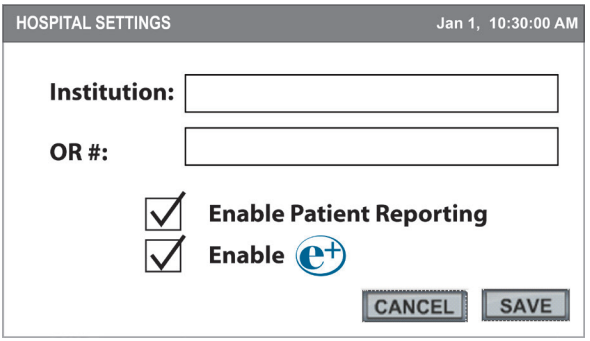
- Audio Level
  Adjust the volume of audio alerts from 1 to 8. Slide volume button to adjust and press SAVE to keep changes.

b) Hospital Settings – allows institution or department name and OR number to be entered and Patient Reporting to be enabled.

- Institution (or department) name and OR number
  Touch the entry field to open touch typing pad. Type name and touch Enter to save and return to Hospital Settings menu.

- Enable Patient Reporting
  Touch the check box to store a viewable record of all completed scans and to allow the patient report to be accessed and displayed.





c) Enable e+

Touch the check box to enable the e+ mode. When enabled the system will adjust dynamically in response to environmental conditions, such as metal near the Body Scanner or large, non-skin contact electrocautery gel pads (e.g. Megadyne® MegaSoft ®) that cover a major area of the RF Antenna Array Body Scanner, and can influence the system performance.

d) Patient Reports – touch to view Patient Report data
Use arrow buttons to scroll through reports.

e) About RF Assure –displays software version and console serial number. No set up required. Touch screen to return to menu.

3) Place the RF Assure Body Scanner and Connect to Console

a) Place the Body Scanner on top of the surgery table pad.

b) Attach the Body Scanner cable plug to the connector labeled "RF Mat"on the console front panel.

- Align the red dots on the plug and connector and press to insert. Ensure the plug is securely fastened in connector.
- When connected the RF Assure Body Scanner icon on the display will illuminate green to indicate a functional Body Scanner. If not, check connections. Replace Body Scanner if the problem persists.

⚠ Caution: Do not connect unauthorized or unrecognized devices to the console.

Use a Body Scanner that is correctly sized for the surgery table torso pad. The Body Scanner should cover full length of the torso pad and be positioned under the surgical site.

Place other devices (patient positioning devices, gel pads, electrocautery and thermal pads etc.) on top of the Body Scanner.

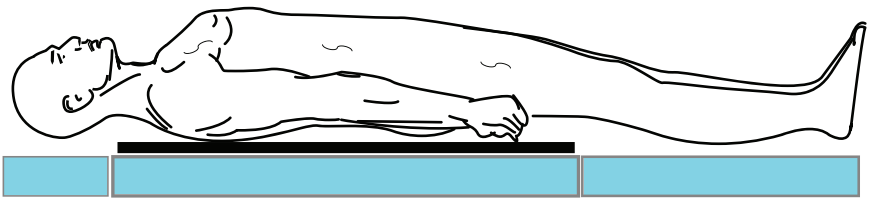
Ensure patient is secure and stable on the surgery table in all table positions expected to be used in the surgical case.

c) Place covers, sterile drapes or other items on the Body Scanner as per standard hospital protocol.

d) The Body Scanner is reusable. Replace if damaged or deteriorated (refer to Care & Cleaning section).

⚠ Caution: Place Body Scanner on top of table pad. Do not place Body Scanner under pad or directly on surgical table frame - metal may interfere with scanning.

If a portion of the Body Scanner is folded over it may result in a scan fault. Ensure Body Scanner lies flat. Do not handle Body Scanner by cable. Store flat.



4) Plug in the Wand - Drape for Reuse

a) Remove the wand from the sterile packaging. Remove the protective cover from the wand plug, if present.

b) Wands intended for reuse must be covered with a sterile drape when removed from the sterile package using sterile/aseptic technique. Inspect wand before use. Replace if damaged or deteriorated (refer to Care & Cleaning section).

⚠ Warning
Wand is packaged sterile. Sterility is assured unless package or seal has been opened or damaged.

c) Draping for Reuse
Select an appropriately sized (16" x 60" minimum) commercially available clear plastic, sterile equipment drape. Follow the hospital procedure for draping non-sterile devices. Ensure all portions of the wand are covered to avoid contamination of the wand and cross-contamination during the operative procedure.

For assistance in selecting a drape, contact the product distributor or RF Surgical® Customer Service.

Dispose of wand according to hospital protocol if damaged, soiled, contaminated, discolored, deteriorated or non-functioning.

d) Attach wand cable to the connector labeled “RF Wand” on the console front panel. Connect while holding wand in the air away from metal for proper calibration.

- Align the plug slot with the horizontal pin on the panel connector and ensure pin is correctly seated in plug.
- Twist plug clockwise to secure it to the connector.

e) Once connected, the “Blair-Port Wand” icon will illuminate. If the display does not show “Blair-Port Wand Press to Scan”, check connection, replace wand or contact sales representative if problem persists.

⚠ Caution

Follow use/reuse instructions. Do not reprocess the wand. Dispose of the wand per hospital protocol.

5) Scan for Tagged Gauze

Ensure all used and unused gauze or gauze packs are removed from the patient area by 36".

a) Scanning

- Touch either the RF Assure Mat or Blair-Port Wand icon to begin scanning.

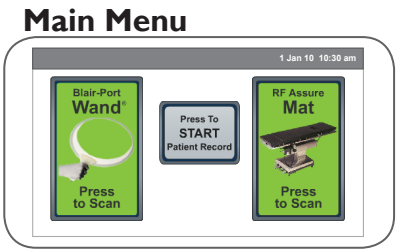
A scan start or stop is indicated by 3 short beeps. While scanning, the selected device is displayed with a status bar and a regular tic sound.

b) RF Body Scanner Scanning

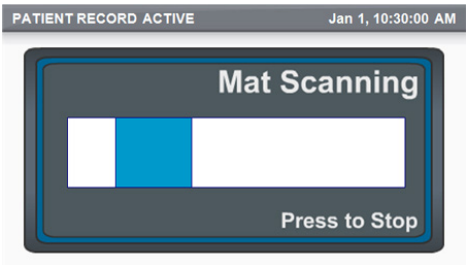
- A tagged sponge/gauze maybe scanned at the start and finish of each scanning procedure for system verification.

- To start a patient record, touch the center icon.

Note: For a patient record, "Enable Patient Reporting" must be checked in the Hospital Settings portion of the Settings & Reports menu. (see Sec 2) part b)

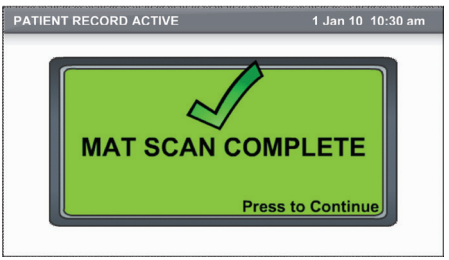


- Patient records are saved and stored by touching the Close Patient Record icon at the end of a completed scan. Records of detections and count reconciliation can be entered at this time.
- Touch the "RF Assure Mat" icon to begin scanning.
- The typical Body Scanner scanning period is 11-15 seconds. Verify the console is in scan mode by observing the scanning status bar and by listening for the regular tic sound.



- The scan can be stopped at any time by touching the screen and returning to the main display.
- If a tag is detected, the display shows “DETECTION” and a solid tone is audible. Touch screen to acknowledge and stop alert. Refer to Scanning Situations and Suggested Responses

- If no tagged objects are detected, the display shows “MAT SCAN COMPLETE”.



c) RF Wand Scanning

- Touch the Blair-Port Wand icon to begin scanning.
- Verify the console is in scan mode by observing the scanning progress bar and by listening for the regular tic sound.

- The Wand scan can be stopped at any time by touching the screen. Unlike the Body Scanner, the Wand scan is continuous but will time out after 3.5 minutes of continuous scanning.
- If a tag is detected during Wand scanning, the display will show "DETECTION" and a solid tone will be audible ONLY while the RF-tagged sponge is within the range of the Wand. A "DETECTION" alert will not stop the scanning process. If the tag is beyond the Wand's range, the screen will return to scanning mode.

NOTE: Unlike the Body Scanner, a Wand scan does not conclude in either a "CLEAR" or "DETECTION" SCREEN.

6) Scan Error

A scan error will cause the scan to stop. The console will display one of the following scan error conditions:

- **Mat Disconnected** - during the scan the Body Scanner was disconnected. Ensure connector is locked into the RF Mat receptacle.
- **Wand Disconnected** - during scan the wand was disconnected.
- **Metal Near Mat – Clear Field Of Metal or Use Wand**
  During the scan, the Body Scanner was in close proximity to the surgical table frame or a metal object such as Mayo stand.
- **Wand Near Metal - Move Metal Away From Scan Site**
  During the scan, the Wand was in prolonged proximity to metal or similar interference.
- **Electrical Interference**
  During the scan, the Body Scanner or Wand sensed a pro longed interference ("noise") from electrical equipment.
- **Move Personnel Back Two Feet From Scan Site**
  The system may be affected by devices on clinical staff. After moving, rescan. If interference is too pervasive for a Body

Scanner scan, the display shows:

- **Mat Scan Inconclusive - Use Blair-Port Wand**
  The wand may be used to complete the scan.

- **Wand Near Mat - Move Wand Away From Mat**
  The wand cannot be placed directly on the Body Scanner during a scan.

- **Verify Mat is Positioned Correctly And Metal Is Not In Scan Area. If Error Persists Replace Mat**
  The Body Scanner may be folded onto itself, have an error, or there may be excessive metal near the Body Scanner.

7) Detection

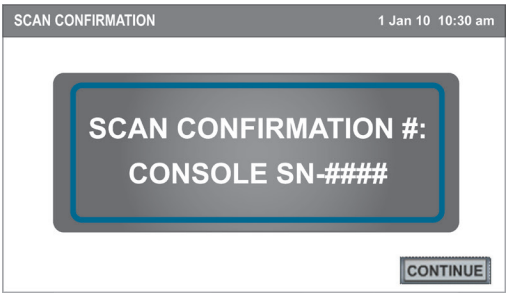
If the system signals a detection remove the tagged object and rescan patient to ensure that all tagged objects have been removed.

Scanning Situations and Suggested Responses

	Detection Indicated	No Detection Indicated
Count Incorrect	•Recount •Look for sponge and remove •Re-scan patient •X-ray if no sponge found	•Re-scan •Look for sponge and remove •Look in trash and linen bag •X-ray if no sponge found
Count Correct	•Recount •Re-scan patient •Look for sponge and remove •X-ray if no sponge found	•Follow normal hospital procedures

8) Scan Confirmation & Reports

A Scan Confirmation number will be displayed after a scan is completed with no errors. Write the scan confirmation number in the patient's medical record to document a completed scan.

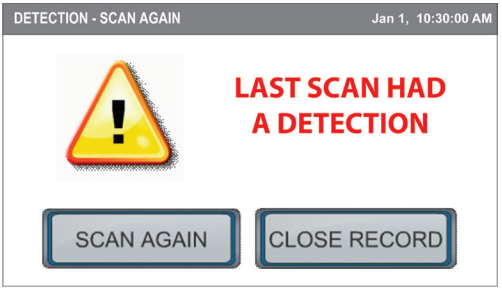


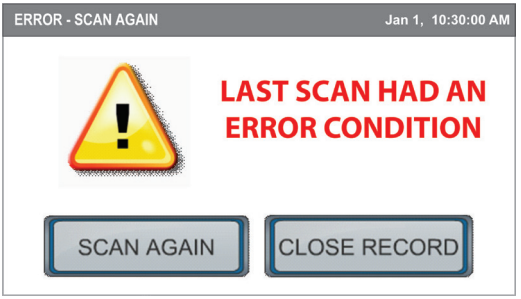
Enable Patient Reporting

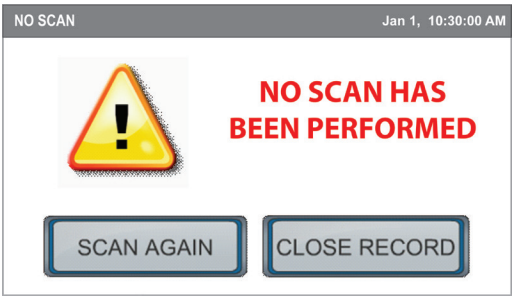
If patient reporting is enabled, (see Sec.2 Console Settings and Reports, b) Hospital Settings), when record is closed, the Scan Confirmation number and patient record information is stored in the console memory and can be accessed in the Patient Reports section of the Settings & Reports menu.

When patient reporting is not enabled, the Scan Confirmation number is not viewable in the Patient Reports and cannot be accessed by the user.

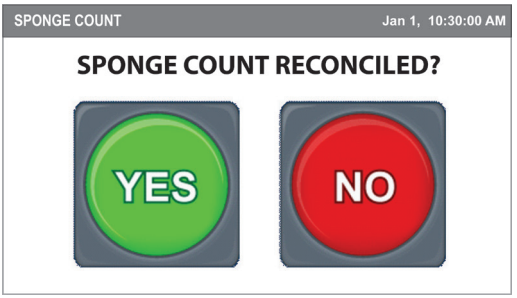
Before closing a patient record, the following displays will indicate scans with detections, scans with errors or no scan conditions.



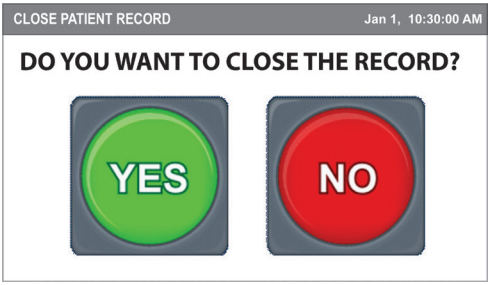




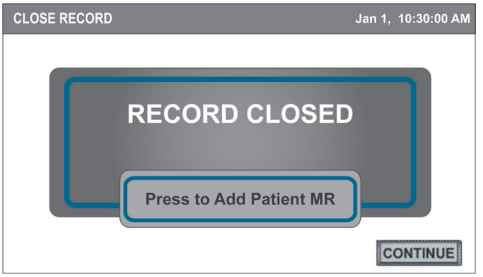
After selecting CLOSE RECORD, indicate the status of the sponge count.



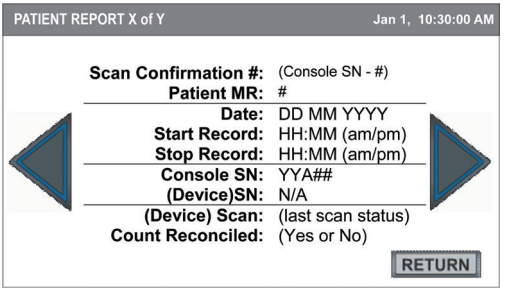
Then verify that the patient record will be closed.



Press to Add Patient MR to enter the MR number and save to the patient report files.



Access records by selecting **Patient Reports** in the **Settings and Reports** menu (see sec.2) Console Settings and Reports**.** Use the arrow keys to select desired report.



Wand Scanning Patterns

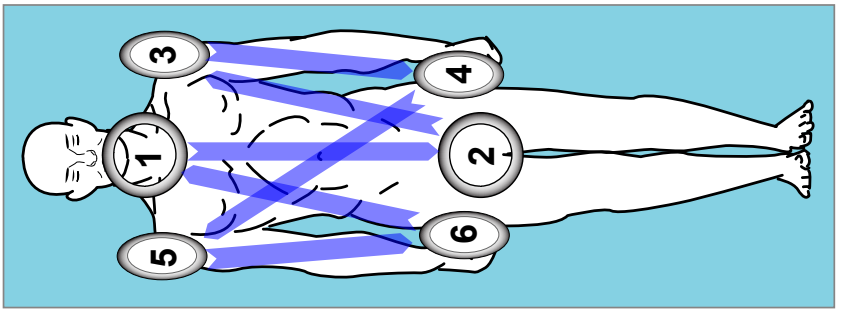
Wand scanning adds an extra measure of assurance to patient scans and allows detection around and outside the surgical site. The following instructions guide the use of the wand in patient scans.

- A tagged sponge/gauze may be scanned at the start and finish of each scanning procedure for System verification.

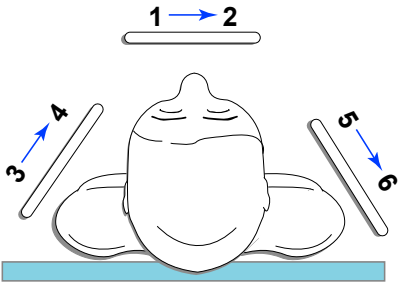
- Move the wand at a steady rate of up to 6 inches per second. Scan low and slow, close to the patient's body.

- To ensure thorough scanning for various tag orientations, the wand must follow the scan pattern over the contour of the patient's body.

- Each scanning procedure includes a vertical scan and a horizontal scan.

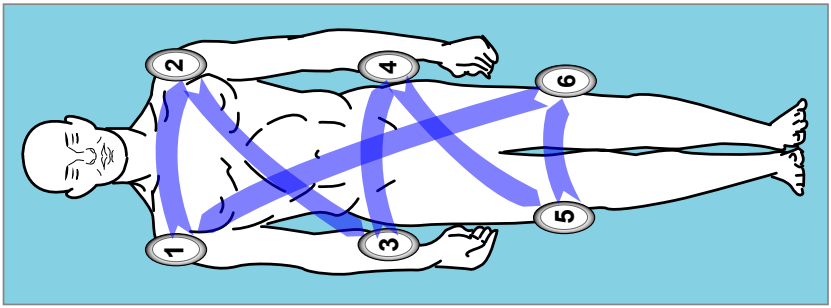


Vertical Wand Scan — Full Pattern

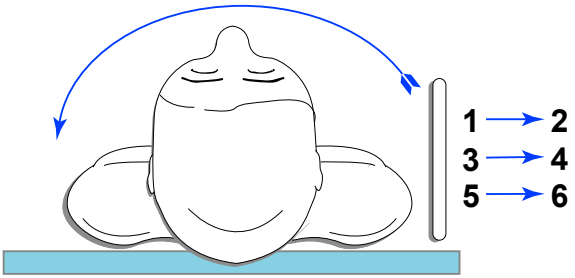


End View of Vertical Wand Scan Pattern

1. Position wand as close as possible parallel to body at Position 1.
2. With wand remaining parallel to body, move wand distally from Position 1 to Position 2.
3. Continue scanning through numeric sequence at a rate of 3 seconds per pass. Passes 3 to 4 and 5 to 6 are performed with wand positioned on lateral sides of torso, parallel to the body.
4. Final pass will return wand from Position 6 back to starting Position 1.



Horizontal Wand Scan — Full Pattern



End View of Horizontal Wand Scan Pattern

1. Place wand on lateral side of torso, parallel to body at Position1.
2. With wand remaining parallel to body, move wand in arc to opposite lateral torso from Position 1 to Position 2.
3. Continue scanning through numeric sequence, at a rate of 3 seconds per pass.
4. Final pass will return wand from Position 6 back to starting Position 1.

Power Down the System

Turn off the power switch on the back panel to power down the system, return to the Main Menu. The console may be unplugged and moved as needed. The Hospital Settings for OR number may be changed in the Console Settings and Reports menu.

NOTE: Disconnect the main power by pulling the plug, not the cord.

Care and Cleaning

Before or after use, inspect the wand and Body Scanner for damage and deterioration including abrasion, cracks, splits, punctures and loose components. Check cables for kinks or breaks in insulation and connectors for wear or damage that would prevent secure attachment.

The console, Body Scanner and wand may be cleaned with an isopropyl alcohol based germicidal wipe, such as PDI Sani-cloth® No.689072. Avoid excessive exposure to fluids and cleaning products. Do not submerge. Avoid fluid ingress to any electrical circuitry.

Disposal

The Blair-Port Wand® and tagged gauze are supplied in sterile packaging. Dispose of wand and gauze product per standard hospital protocol.

For disposal of the console and Body Scanner, contact the distributor or manufacturer. Please only return cleaned or disinfected products to supplier.

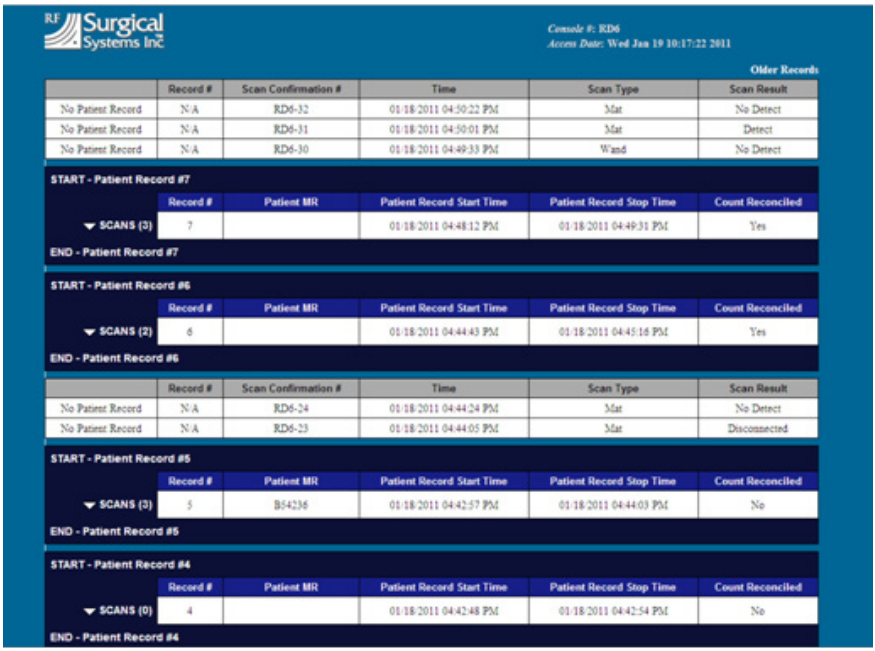
Patient Records - Remote Access

The RF Assure Detection System allows scan records to be accessed from a remote computer when properly configured using an internet web address.

Recommendation:

Manually set console Ethernet configuration for a static IP address. Check with hospital IT department for appropriate settings.

1. Connect Ethernet cable to console input on back panel
2. Press the recessed button the back panel to access "Settings and Reports" menu.
3. Select "Console Settings"
4. Select "Ethernet Settings". Record the IP address – it is the web access address for the console records.
5. Access the patient records from any computer that is connected to the same hospital network as the console.
6. Launch an internet browser e.g., MS Internet Explorer®, and enter the IP address in the web address bar (no "www"is required). Press enter. The Patient/Scan Records screen should be displayed.


RF Surgical Systems Inc

Console #: RD6
Access Date: Wed Jan 19 10:17:22 2011

Older Records

	Record #	Scan Confirmation #	Time	Scan Type	Scan Result
No Patient Record	N/A	RD6-32	01/18/2011 04:50:22 PM	Mat	No Detect
No Patient Record	N/A	RD6-31	01/18/2011 04:50:01 PM	Mat	Detect
No Patient Record	N/A	RD6-30	01/18/2011 04:49:33 PM	Wand	No Detect

START - Patient Record #7

	Record #	Patient MR	Patient Record Start Time	Patient Record Stop Time	Count Reconciled
▼ SCANS (3)	7		01/18/2011 04:48:12 PM	01/18/2011 04:49:31 PM	Yes

END - Patient Record #7

START - Patient Record #6

	Record #	Patient MR	Patient Record Start Time	Patient Record Stop Time	Count Reconciled
▼ SCANS (2)	6		01/18/2011 04:44:43 PM	01/18/2011 04:45:16 PM	Yes

END - Patient Record #6

	Record #	Scan Confirmation #	Time	Scan Type	Scan Result
No Patient Record	N/A	RD6-24	01/18/2011 04:44:24 PM	Mat	No Detect
No Patient Record	N/A	RD6-23	01/18/2011 04:44:05 PM	Mat	Disconnected

START - Patient Record #5

	Record #	Patient MR	Patient Record Start Time	Patient Record Stop Time	Count Reconciled
▼ SCANS (3)	5	B54236	01/18/2011 04:42:57 PM	01/18/2011 04:44:03 PM	No

END - Patient Record #5

START - Patient Record #4

	Record #	Patient MR	Patient Record Start Time	Patient Record Stop Time	Count Reconciled
▼ SCANS (0)	4		01/18/2011 04:42:48 PM	01/18/2011 04:42:54 PM	No

END - Patient Record #4

7. “START - Patient Record” and “END - Patient Record” rows are displayed for each patient record.

START - Patient Record #7
Record # | Patient MR | Patient Record Start Time | Patient Record Stop Time | Count Reconciled
SCANS (3)
7 | | 01/18/2011 04:48:12 PM | 01/18/2011 04:49:31 PM | Yes
END - Patient Record #7

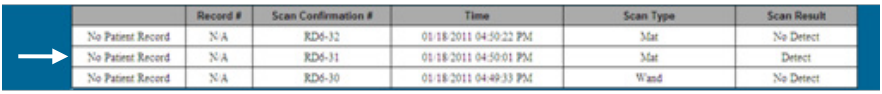
8. The number of scans in a patient record is indicated in parenthesis after “SCANS”.

START - Patient Record #7
Record # | Patient MR | Patient Record Start Time | Patient Record Stop Time | Count Reconciled
SCANS (3)
7 | | 01/18/2011 04:48:12 PM | 01/18/2011 04:49:31 PM | Yes
END - Patient Record #7

9. Select the “SCANS” link to view all scans associated with the patient record.

START - Patient Record #7
Record # | Patient MR | Patient Record Start Time | Patient Record Stop Time | Count Reconciled
SCANS (3)
7 | | 01/18/2011 04:48:12 PM | 01/18/2011 04:49:31 PM | Yes
Record # | Scan Confirmation # | Time | Scan Type | Scan Result
7 | RD6-27 | 01/18/2011 04:48:16 PM | Mat | Detect
7 | RD6-28 | 01/18/2011 04:48:46 PM | Mat | Metal Interference
7 | RD6-29 | 01/18/2011 04:49:11 PM | Mat | No Detect
END - Patient Record #7

10. When a scan is performed without starting a patient record “No Patient Record” is displayed.


Record # | Scan Confirmation # | Time | Scan Type | Scan Result
No Patient Record | N/A | RD6-32 | 01/18/2011 04:50:22 PM | Mat | No Detect
No Patient Record | N/A | RD6-31 | 01/18/2011 04:50:01 PM | Mat | Detect
No Patient Record | N/A | RD6-30 | 01/18/2011 04:49:33 PM | Wand | No Detect

11. Select the “Older Records” or “Newer Records” link to parse through all records.

RF Surgical Systems Inc
Console #: RD6
Access Date: Wed Jan 19 10:20:52 2011
Newer Records
Older Records
START - Patient Record #2
Record # | Patient MR | Patient Record Start Time | Patient Record Stop Time | Count Reconciled
SCANS (2)
2 | E52417 | 01/18/2011 04:41:11 PM | 01/18/2011 04:42:25 PM | Yes
Record # | Scan Confirmation # | Time | Scan Type | Scan Result
2 | RD6-17 | 01/18/2011 04:41:20 PM | Mat | Electrical Interference
2 | RD6-18 | 01/18/2011 04:41:54 PM | Mat | No Detect
END - Patient Record #2

12. Press the Refresh symbol to the right of the web page address for up to the minute record access.

Troubleshooting

The following table identifies possible system problems and provides suggestions for resolving the problem.

Symptom	Action
Display does not illuminate	• Check power cord connections. • Ensure power switch is in the ON position. • Verify the wall outlet is active. • If display remains dark, contact your RF Surgical® sales representative or distributor.
Display is white and/or touch screen is not responsive	• Cycle power to restart console. If problem persists, contact your RF Surgical® sales representative or distributor.
Erratic operation or display	• Cycle power to restart console. If problem persists, contact your RF Surgical® sales representative or distributor.
No sound from the console	• Replace console. Contact your RF Surgical® sales representative or distributor.
RF Assure Mat icon does not illuminate green or displays MAT ERROR	• Ensure Body Scanner connector is locked to console receptacle. • If RF Assure Mat icon remains dark or displays error, replace Body Scanner.
Blair-Port Wand icon does not illuminate green or displays WAND ERROR	• Check that wand is properly plugged in. • Wand is non-functional. • Replace wand if problem persists.
“Mat Disconnected” displayed	Body Scanner disconnected during scan. Check connection. Replace Body Scanner if problem persists.

“Wand Disconnected” displayed	Wand disconnected during scan. Check wand connection and condition. Replace wand if problem persists.
“Metal Near Mat” displayed	Large metal object in close proximity to Body Scanner during scan. Remove metal object. Check placement of Body Scanner on table pad. Use Blair-Port wand to scan.
“Wand Near Metal” displayed	Wand in prolonged proximity to metal object such as a Mayo stand. Remove metal object from scan area.
“Electrical Interference” displayed	Prolonged interference (“noise”) from other electrical equipment or power source. Remove or turn off equipment. Scan with wand.
“Move Personnel Back” or “Device Interference” displayed	RFID source (car keys, badges) in the scan area. Remove source of interference. Clinical staff wearing such items should step back from scan area during the scan.
Prolonged Body Scanner scan time	No action required – console software is filtering environmental conditions to acquire optimum signal.
“Mat Scan Inconclusive” displayed	Interference is affecting Body Scanner scan. Use wand.
“Verify Mat is Positioned Correctly And Metal Is Not In Scan Area. If Error Persists Replace Mat” displayed	The Body Scanner may be folded onto itself, have an error, or there may be excessive metal near the Body Scanner.
“L&D Mat Connected. Replace with OR Mat” displayed	L&D mat is not designed for use with the Model 200/200E console. Replace with an RF Assure Antenna Array Body Scanner.

The estimated life for the console is 3 years and for the wand and Body Scanner is 1 year under normal use conditions as described in this DFU. Suspected faulty product should be returned to RF Surgical for evaluation. If you encounter a problem using the System that you cannot resolve, contact your RF Surgical® sales representative or distributor.

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Carlsbad, CA 92008 USA
Tel 760.827.1500 www.rfsurg.com
US Patent #6,026,818 Other Patents Pending

Emergo Europe
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2513 BH The Hague
The Netherlands
EC REP

CE 0470

Warnings and Cautions

⚠ Warnings

• To avoid risk of electrical shock, this equipment must only be connected to supply mains with protected earth (ground). Do not place console to obstruct access to power switch or power plug connection.

• The system has been designed to detect tagged items at a range up to 16” (40.64cm).

DANGER
• Risk of explosion if used in the presence of flammable anesthetics.

⚠ Cautions

• Do not move the wand at a rate faster than 6” per second. Exceeding this rate may diminish the system’s ability to detect tagged objects.
• Remove large metal objects, trays and Mayo stands from the scan site before scanning. Metallic objects in the scan area or in close contact with the tag may attenuate the signal and affect the System’s ability to detect tagged objects.
• Ensure all known tagged objects are more than 36” from the scan site to avoid possible false positive detections.
• Remove RFID devices (badges, car keys) away from the scan area to avoid scan interference.

• Limit the use of electrical equipment such as RF electrosurgery instruments (Bovies) during scanning, and power down unused electronic devices and instruments. If possible, be sure all electronic equipment is at least 36" from the scan site. Concurrent use of some electrical equipment in close proximity to the surgical scanning site may affect the System's ability to detect tagged objects. Some types of electrical equipment in close proximity to the surgical scanning site may cause false detections.

Examples:

-Fluoroscope
-Notebook computers
-CRT monitors
-Headlamp base unit (e.g., Welch Allyn Solarc)
-Heat-controlled blankets (e.g., Bair Hugger®)
-Endoflator
-Electrosurgery generator (e.g., Bovie)
-Constricting units (e.g., Veso)
-MRI Systems
-Freeze Probe
-Defibrillator
-Ultrasound Equipment
-Electronic / magnetic / RF identification badges and keys

• Independent laboratory testing[1] and extensive hospital clinical experience demonstrate that the RF Surgical Detection can be compatible with most commonly used pacing and defibrillator devices when used in accordance with the manufacturers' directions and hospital protocol. Refer to the pacing or defibrillator device manufacturer's instructions, hospital protocol and these directions for use to ensure optimal operation of these devices. Scanning may affect temporary cardiac pacers in demand mode settings (DDD). Temporary cardiac pacers should be set to non-sensing, asynchronous mode (VOO or DOO mode) during scanning.

Do not program pacing or ICD devices while scanning. Follow the pacing or defibrillator device manufacturer's instructions to achieve desired programming settings.

[1] *Study by RF Surgical Systems at the Arrhythmia Technologies Institute, Greenville, South Carolina, June 3, 2011, of multiple common implantable and temporary cardiac pacing devices and internal cardiovertor/defibrillator devices in simulated clinical use in conjunction with the RF Surgical Detection System.*

- Magnets are known to block the tag signal when in close proximity to the tag.

- Large, non-skin contact electrocautery gel pads (e.g., Megadyne® Mega Soft®) that cover a major area of the Body Scanner may affect the Body Scanner's detection range. Enable the e+ mode via the Hospital Settings menu or use the Blair-Port Wand for scanning with such devices.

- Interruptive electromagnetic interference may be caused by MRI, power transformers or other high power sources.

- MRI Usage- Follow hospital protocol, device manufacturers' directions for use and established clinical practice by trained staff in the use of MRI. Independent laboratory testing with regard to translational attraction, migration and torque as well as MRI-related heating indicates that RF-tagged gauze, sponges and towels present no additional risk or hazard to a patient in an MRI environment of up to 3 Tesla should a sponge/gauze product be present in a post-operative patient. No authoritative testing has been conducted to date on intraoperative MRI use with RF-tagged gauze or sponges.

- The RF Assure Console has no user serviceable parts, and preventative maintenance is not required. To reduce the risk of electrical shock, do not disassemble unit. Return to manufacturer per Warranty.

- Never touch the console interface connection (USB or LAN) and the patient at the same time.

- Only connect IEC 60601-1 or RF Surgical approved devices to the USB interface. The user must ensure that the interconnected system maintains leakage currents according to IEC 60601-1.

- The RF tag in direct contact with metal will reduce the tag signal and impair scanning. Avoid direct metal contact within 1mm of the tag. If sponge sticks are used, wrap a layer of gauze >1mm between tag and instrument.

- Some labor and delivery birthing beds produce excessive electrical noise from power units (e.g., Hill-Rom® Affinity® Model 3 and 4 birthing beds and Advanta™ recovery beds). Do not perform detection scanning on these beds unless they have been updated by the manufacturer to reduce electrical noise. Alternate scanning methods, such as a wheelchair scan, are available.

Specifications

General – RF Assure Antenna Array Body Scanner

Size		
Length	39.25”	(99.7 cm)
Width	20.75”	(52.7 cm)
Thickness	0.625”	(1.6 cm)
Weight	11 lb	(5 Kg)
Connector Type	Push Pull Lock Plug	
Cord Length	12 ft	(4.6 m)
Cord Type	Shielded	

General – Blair-Port Wand

Size		
Max Length	19.25”	(48.9 cm)
Outer Diameter	14.75”	(37.5 cm)
Thickness	0.625”	(1.6 cm)
Weight	11 oz	(312 g)
Connector Type	BNC	
Cord Length	9 ft	(2.7 m)
Cord Type	Coaxial	

General – RF Assure Console Model 200/200E

Size	9.75” x 11.75” x 4.5” (24.8 cm x 29.8cm x 11.4 cm)	
Weight		
Console	7 lbs	(3.2 kg)
Console & Power Cord	7.5 lbs	(3.4 kg)
Connector Type	BNC and Push-Pull Lock Receptacle	
Cord Length	8-15 ft	(2.5 - 5 m)
120V System		
Power Input	100-240 V~ ± 10%, 60VA, 50/60 Hz	
Fuses (Qty 2)	250 V, T500 mA	

Environmental

Operating Temperatures	10°C to 40°C
Relative Humidity	10% - 90% Noncondensing
Storage/Transportation Temperature	-40°C to 70°C
Storage Atmospheric Pressure	500 hPa to 1060 hPa
Operating Altitude	< 2000 m

Safety Classifications

Mode of Operation	Continuous Operation
External Electrical Power Source	Class I Equipment
Degree of Protection against Electric Shock	Type B Equipment
Ordinary Equipment	
Not protected against water ingress	IPXO
General Safety	
Medical Electrical Equipment	IEC 60601-1
EMC Emissions/Immunity- Medical	
Medical Electrical Equipment	IEC 60601-1-2

Note: The wand and Body Scanner emit a 145kHz low power electromagnetic signal to detect the tag. The level of emitted radiation is below the prescribed levels per IEC 60601-1-2 and does not pose risk to the patient or user.

Manufacturer's Declaration

The following tables contain the manufacturer's declaration for the RF Assure Model 200 Detection System electromagnetic emissions, electromagnetic immunity, and recommended separation distances between the RF Assure Model 200 Detection System and portable and mobile RF communications equipment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The RF Assure Model 200 Detection System is intended for use in the electromagnetic environment specified below. The customer or the user of the RF Assure Model 200 Detection System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 2	The RF Assure Model 200 Detection System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The RF Assure Model 200 Detection System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The RF Assure Model 200 Detection System is intended for use in the electromagnetic environment specified below. The customer or the user of the RF Assure Model 200 Detection System should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV ± 8 kV air	± 4 kV ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Avoid using in high ESD environment.

Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	AC power (“mains”) quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	AC power (“mains”) quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (> 95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (>95% dip in UT) for 5 s	< 5% UT (> 95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (>95% dip in UT) for 5 s	AC power (“mains”) quality should be that of a typical commercial or hospital environment. If the user of the RF Assure Model 200 Detection System requires continued operation during power mains interruptions, it is recommended that the RF Assure Model 200 Detection System be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The RF Assure Model 200 Detection System is intended for use in the electromagnetic environment specified below. The customer or the user of the RF Assure Model 200 Detection System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 Vrms
Radiated RF IEC 61000-4-3	Radiated RF 80 MHz to 2.5 GHz	3 V/m

Portable and mobile RF communications equipment should be used no closer to any part of the RF Assure Model 200 Detection System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance
$d = 0.35\sqrt{P}$
$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

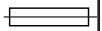
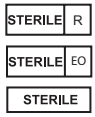
Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [ME EQUIPMENT or ME SYSTEM] is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT or ME SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be
necessary, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM].

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Symbol Descriptions

	Interference		Consult Operating Instructions
	CE Mark		CSA Mark
	Caution		Use By
	Lot Number		Serial Number
	Manufacturer		Date of Manufacture
	Type B Equipment		Waste Electrical and Electronic Equipment
	Fuse		Protective Earth Ground
	Sterilized using Irradiation Sterilized using EO Sterile		Do Not Re-Sterilize Not Sterilized
	Do Not Re-use		Do Not Use if Package is Damaged
	Keep Dry		No Latex
	Temperature Limitations		Atmospheric Pressure Limitations
	Humidity Limitations		Authorized Representative in European Community
	USB Port		Ethernet Port

RF Surgical® Warranty

Limited Warranty/Disclaimer

The Company warrants only that the System will be free from defects in material or workmanship under normal use and service for a period of one (1) year from the date of delivery to you. Wands and Body Scanners deemed non-functional with no damage or deterioration due to abnormal use, will be replaced at no cost. Wands or Body Scanners deemed to be damaged from abnormal use may need to be re-purchased for replacement by the user. EXCEPT FOR THE FOREGOING LIMITED WARRANTY, THE COMPANY MAKES NO WARRANTIES, EXPRESS, IMPLIED OR STATUTORY, AS TO THE NON-INFRINGEMENT OF THIRD-PARTY RIGHTS, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE. THE COMPANY DOES NOT AND CANNOT WARRANT THE PERFORMANCE OR RESULTS YOU MAY OBTAIN BY USING THE SYSTEM. IF APPLICABLE LAW REQUIRES ANY WARRANTIES WITH RESPECT TO THE SYSTEM, ALL SUCH WARRANTIES ARE LIMITED IN DURATION TO ONE (1) YEAR FROM THE DATE OF DELIVERY. Some states do not allow the exclusion of implied warranties or limitations on how long an implied warranty may last, so the above limitations may not apply to you. This Limited Warranty gives you specific legal rights and you may also have other rights, which vary from state to state.

Limitation of Liability

IN NO EVENT WILL THE COMPANY BE LIABLE TO YOU FOR ANY SPECIAL DAMAGES, INCLUDING ANY LOST PROFITS, LOST SAVINGS, OR OTHER INCIDENTAL OR CONSEQUENTIAL DAMAGES, EVEN IF THE COMPANY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, OR FOR ANY CLAIM BY ANY OTHER PARTY. Some states do not allow the exclusion or limitation of special, incidental, or consequential damages, so the above limitation may not apply to you.

Limitation of Remedies

The Company's entire liability and your exclusive remedy under the Limited Warranty (see above) shall be the replacement of any System that is returned to the Company and does not meet the Company's Limited Warranty. If the Company or its distributor is unable to deliver a replacement System, your money will be refunded.